From: DiNatale, Margaret (DPH)

Sent: Thursday, June 11, 2009 3:40 PM

To: Nassif, Julianne (DPH)

Subject: RE:

Hi Julie,

OK – anytime on Monday will work for me. You can book or re-book in Outlook.

Discussions:

- 1. Reference SOP: Is it an AOAC SOP? Does the AOAC SOP state use of multiple volumes? Does AOAC SOP state different calculations for different volumes?
- 2. Since this is a "new" clinical assay, we must have documentation of method verification. New in CLIA terms is new to lab, change in intended use of an assay, change in test reagents, change in sample volumes, change in reagent volumes, to list a few. I will bring copies of the handout on New Test Implementation to the meeting as a reference. I think Jill attended that session and she should have the handouts.

I think that should hit the high points.

Thanks, Peggy

From: Nassif, Julianne (DPH)

Sent: Thursday, June 11, 2009 3:32 PM

To: DiNatale, Margaret (DPH)

Subject:

Hi peg,

Got your message. Let's meet to discuss the broader issues on Monday. Thanks, Julie

Julianne Nassif

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